Customer and Employee Relations Directorate

(CaER)

ISO 9000 Implementation Team

Audit Preparation

Handbook

September 4, 2002

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1.0 Purpose

Marshall Space Flight Center has been assessed and approved by National Quality Assurance, U.S.A against the following quality assurance management system standard: ISO9001: 1994. On May 15, 1998. ISO 9001:2000 on November 29, 2001.

"The Quality Management System is applicable to all processes for procurement, design, development, and onsite production of flight hardware, flight software, and associated ground support equipment interfacing with flight hardware and software, for which MSFC has responsibility."

In order to continue our registration, MSFC is required to pass the Surveillance Audit every 6 months. The Surveillance Audit is to ensure that MSFC continue to meet the requirements. The next Surveillance Audit for ISO 9K:2K and AS 9100 is scheduled for June 17, 18, 2003.

MSFC ISO representative, Mr. Axel Roth directed all center organizations be prepared for ISO9001: 2000 Surveillance Audit and AS 9100

The purpose of this document is to provide guidelines to assist all CaER directorate employees in this upcoming audit preparation.

2.0 Audit requirements

2.1 New Standard ISO 9001:2000 clauses

4.2.1 Document Requirements
4.2.4 Quality Records
5.4.1 Quality Objectives
5.6 Management Review
7.1 Planning of Product Realization
7.2 Customer-Related processes & Communicaton
7.5.1 Control of Production and Service Provision
7.5.3 Identification and Traceability
8.2.1 Customer Satisfaction
8.5.1 Continual Improvement
8.5.2 Corrective action
8.5.3 Preventive action
1 Scope
    a. General
    b. Application

2 Normative reference
3 Terms and definition

4 Quality management system
    4.1 General requirements

    4.2 Documentation requirements
        4.2.1 General
        4.2.2 Quality manual
        4.2.3 Control of documents
        4.2.4 Control OF records

5 Management responsibility
    5.1 Management commitment
    5.2 Customer focus
    5.3 Quality policy
    5.4 Planning
        5.4.1 Quality objectives
        5.4.2 Quality management system planning
    5.5 Responsibility, authority and communication
        5.5.1 Responsibility and authority
        5.5.2 Management representative
        5.5.3 Internal communication
    5.6 Management review
        5.6.1 General

5.6.2 Review input
5.6.3 Review output

6 Resource management
6.1 Provision of resource
6.2 Human resources
6.2.1 General
6.2.2 Competence, awareness and training
6.3 Infrastructure
6.4 Work environment

7 Product realization
7.1 Planning of product realization
7.2 Customer related process
7.2.1 Determination of requirements related to the product
7.2.2 Review of requirements related to the product
7.2.3 Customer communication
7.3 Design and development
7.3.1 Design and development planning
7.3.2 Design and development input
7.3.3 Design and development output
7.3.4 Design and development review
7.3.5 Design and development verification
7.3.6 Design and development validation
7.3.7 Control of design and development changes

7.4 Purchasing
7.4.1 Purchasing process
7.4.2 Purchasing information
7.4.3 Verification of purchased product
7.5 Production and service provision
7.5.1 Control of production and service provision
7.5.2 Validation of processes for production and service provision
7.5.3 Identification and traceability
7.5.4 Customer property
7.5.5 Preservation of product

7.6 Control of monitoring and measuring devices

8 Measurement, analysis and improvement
8.1 General

8.2 Monitoring and measurement
    8.2.1 Customer satisfaction
    8.2.2 Internal audit
    8.2.3 Monitoring and measurement of processes
    8.2.4 Monitoring and measurement of product
8.3 Control of nonconforming product
8.4 analysis of data
8.5 Improvement
    8.5.1 Continual improvement
    8.5.2 Corrective action
    8.5.3 Preventive action

2.2 NQA Surveillance Audit for ISO 9K:2K

NQA Surveillance Audit for ISO 9K:2K, June 17, 18, 2003

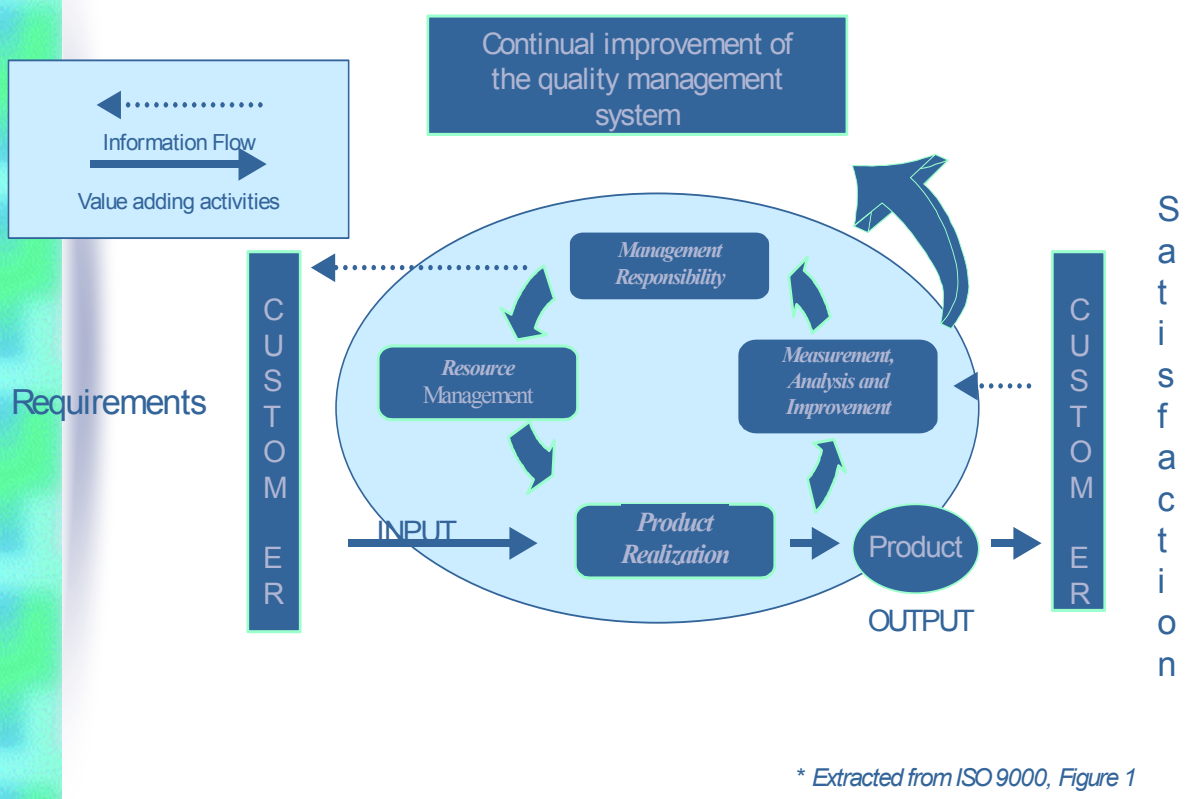
Upcoming Audit preparation
http://iso9000.msfc.nasa.gov:9001/internal_audits/helpful_hints.htm

Audit preparation exercise.
http://iso9000.msfc.nasa.gov:9001/introductions/tools.html

- Do What You Say, and Say What You Do.
- System Evaluation Approach
- Plan, Do, Check, Act
- Focus on Quality Plans and Procedures and How the Plan Structure Supports Effectiveness Measures
- View Organizations Approach fro Continuity Throughout Organization (Vision-Objectives-Metrics-Analysis)
- Understand Quality Records Structure and its Approach fro Controlling Information/Data
- Evaluate Performance Measures Infrastructure and Resultant Data

NATIONAL QUALITY ASSURANCE, USA

Quality Management Process Model



* Extracted from ISO 9000, Figure 1

3.0 Audit Schedule

CaER Internal Audit: September 22-26, 2003

NQA Surveillance Audit for ISO 9K:2K, and AS 9100 on June 17, 18, 2003

4.0 Internal/Internal Audit preparation Check List

4.1 Audit Preparation Check List for New Scope and New Standard.
Knowledgeable about:

4.1.1 MSFC's Quality Policy
http://iso9000.msfc.nasa.gov:9001/introductions/policy.html
Marshall's Management Manual
https://repository.msfc.nasa.gov/RightSite/getcontent/tempfile.pdf?DMW_FORMAT=pdf&DMW_OBJECTID=090033db8008a5a8

4.1.2 Who is MSFC's ISO Management Representative. And why we need to know about that.
http://iso9000.msfc.nasa.gov:9001/responsible/official.html
Who is CaER Directorate Marshall Management System (MMS) Representatives. (MMS used to be the MSFC ISO implementation team)
Primary representative: Caroline Wang/CD30
Alternate representative: Pat Schultz/CD20

4.1.3 Your Job Responsibilities, Products and Services and Customers

4.1.4 MSFC Center Policy, Guidelines, Procedures, and Organizational Work Instruction that you use for your job.
http://inside.msfc.nasa.gov/MIDL/
http://caer.msfc.nasa.gov/owi1.html

Quality Records, where it locates and the record retention schedule.
http://caer.msfc.nasa.gov/recplan.html

4.1.5 How to use MSFC ISO web site,
http://iso9000.msfc.nasa.gov:9001/index.html

4.1.8 CaER directorate ISO web Site
http://caer.msfc.nasa.gov/iso9000.html

4.1.9 How to use the Corrective Action and Preventive Action system
http://caer.msfc.nasa.gov/correct.html

4.1.10 Customer Feed Back
https://msfcsma3.msfc.nasa.gov/dbwebs/apps/qualcomm/

4.1.11 Continual Improvement Success Stories
http://contimp.msfc.nasa.gov/

4.1.12 Quality Objectives

The MSFC Center Director shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

4.1.13 Organizational Work Instructions
The OWI that you use for your work.
http://caer.msfc.nasa.gov/owi1.html

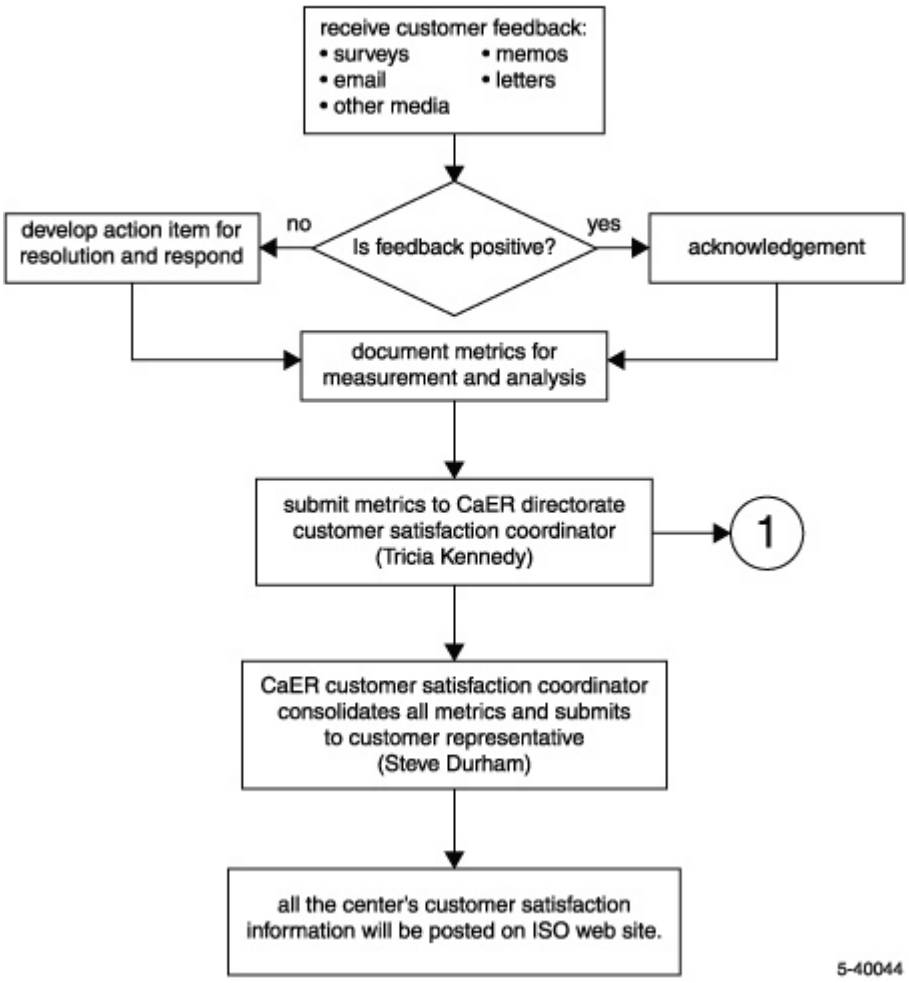
4.2 Customer Satisfaction and Continual Improvement Audit Preparation list

What is your Customer feedback system?

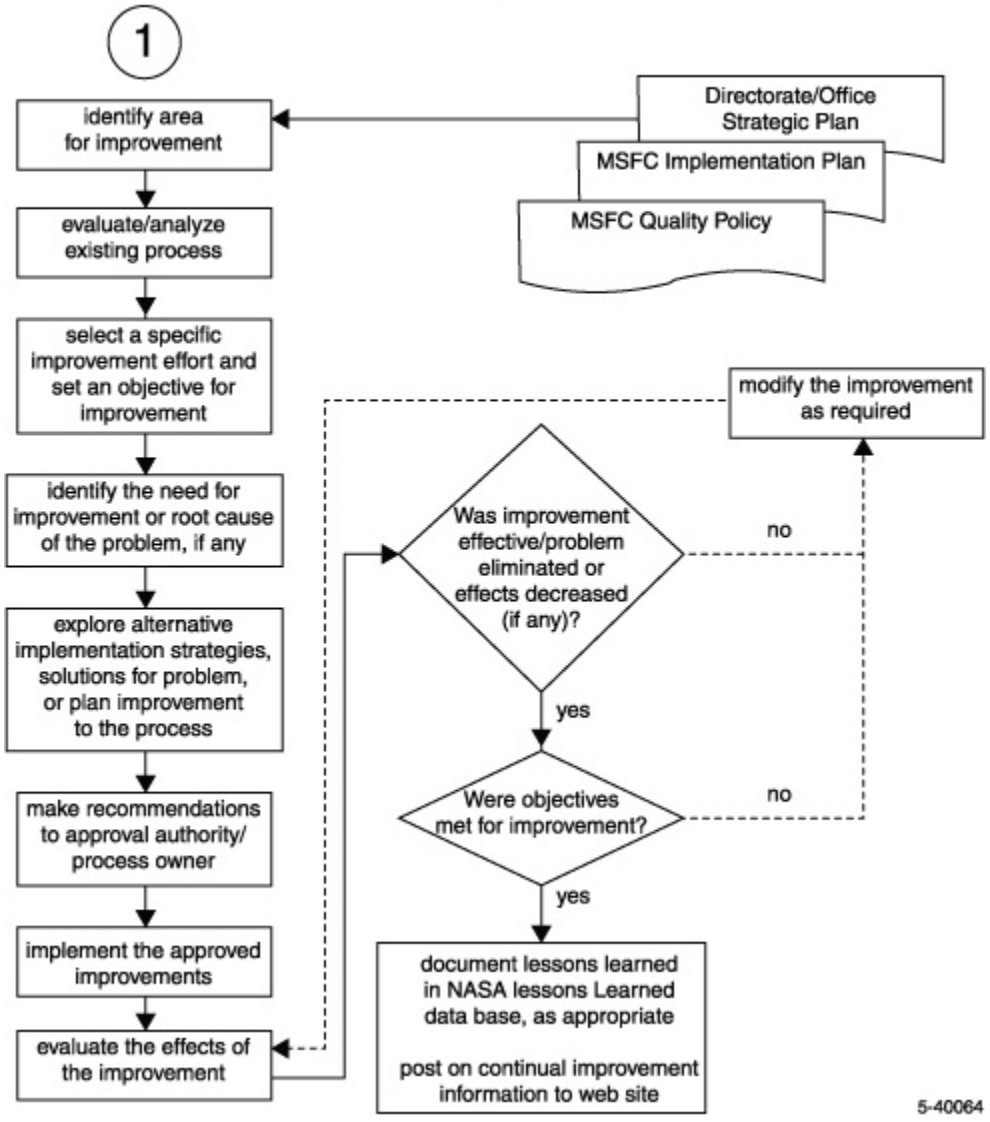
What is your process for continual improvement?

Do you have a performance metrics system?

CaER Customer Satisfaction Continual Improvement (CSCI) Implementation



Continual Improvement Flow



4.3 Document Custodian Audit Preparation Check List

4.2.1 Familiar with CaER Directorate Document Control Process CD01-OWI-001, CaER Document Control Process http://caer.msfc.nasa.gov/docs/cd01-owi-001.pdf

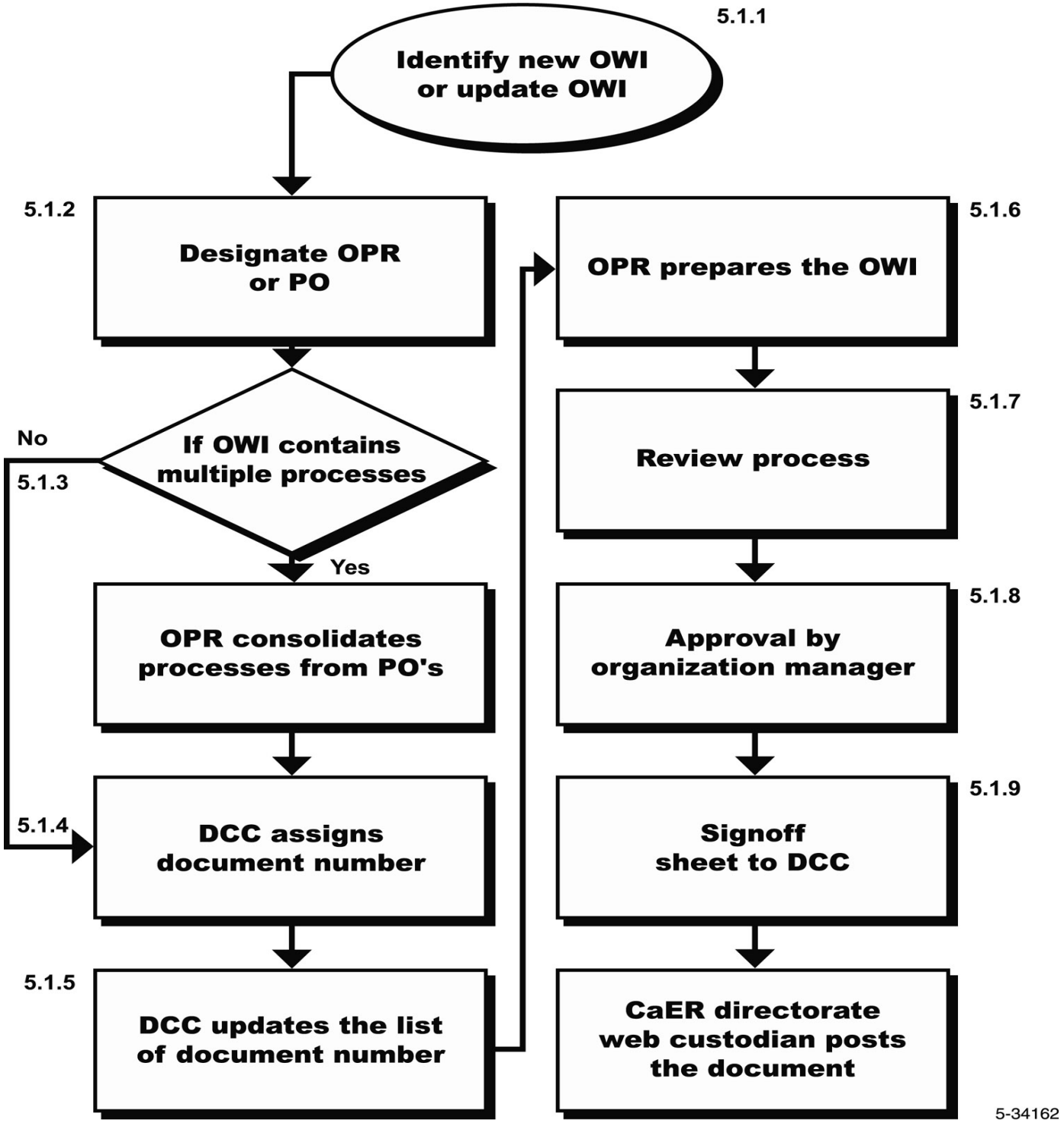
4.2.2 Verify your organization Documents:

4.2.3 Organization Master List

4.2.4 Reference to Obsolete Documents

4.2.5 Ensure that manager reviewed and signed the approval sheet within last 6 months

CaER Directorate OWI's Document Control Process Flow Diagram



4.3 Record Custodian Audit Check List

4.3.1 Familiar with NPG1441.1 Record Retention Schedule
http://nodis3.gsfc.nasa.gov/library/displayAll.cfm?Internal_ID=N_PG_1441_001D_&page_name=all
Familiar with MPG1440.2 MSFC Record Management Plan
https://repository.msfc.nasa.gov/RightSite/getcontent/1440.2J.pdf?DMW_FORMAT=pdf&DMW_OBJECTID=090033db8008a601
Familiar with CD01-OWI-003, CaER Record Management Plan
http://caer.msfc.nasa.gov/docs/cd01-owi-003.pdf

4.3.2 Understand Record Custodian's Responsibility

Record Custodian. The individual who is responsible for collecting, indexing, accessing, filing, storing, maintaining, and dispositioning a record or collection of records.

Records Custodians (RC's) are responsible for maintaining and furnishing information from the records assigned to them. Specific responsibilities include:

Keeping current on the records management regulations and procedures and on the functions of record-keeping offices.

Maintaining an up-to-date Records Plan.

Properly identifying, arranging, and disposing of records in accordance with NPG 1441.1, MPG 1440.2, and the Organizational Work Instructions (OWIs). Retire the record to a Federal Records Center when/as required. (Records retired to a Federal Records Center are maintained in accordance with 44 U.S. C. Chapter 21, 36 CFR Chapter 12, and National Archives and Records Administration procedures.)

Reviewing assigned records at least annually to ensure that only necessary records are being retained.

Coordinating records problems with the Records Liaison Officer or the Marshall Records Manager.
Establishing and maintaining documented procedures/instructions for controlling records (may be included in the applicable procedural document) in conformance with identification of records in the organization's Records Plan.

4.3.3 Familiar with organizational Record Retention Schedule
4.3.4 Ensure that Record Retention Schedule is correct.
4.3.5 Ensure that all records are located at the place that Record Retention Schedule indicated.
4.3.6 Ensure that OWI, Quality Records are consistent with the Record Retention Schedule data.

4.4 Safety Coordinator's Audit Check List

4.4.1 Safety meeting minutes, sign in sheet (Monthly)
4.4.2 Safety walk through records (Safety violations records)
4.4.3 Fire Extinguishes monthly checkup
4.4.4 All Employees are familiar with Central SHE and the purpose
4.4.5 All Employees must have JHA
4.4.6 Housekeeping rules must be posted and followed.

4.5 Credit Card Owner Audit Check List

4.5.1 Familiar with MWI 5113. 1E Government wide commercial purchase card operating procedure
https://repository.msfc.nasa.gov/RightSite/getcontent/5113.1E.pdf?DMW_FORMAT=pdf&DMW_OBJECTID=090033db8004e27c

4.5.2 What is purchase limit for a single order, and what is monthly limit?

4.5.3 Where can you find the vendor code you need for a purchase?

4.5.4 Purchase Record

4.5.5 Who is your primary Signature authority, and alternate signature authority

4.6 Manager Audit Check List

What is your job?

How has the quality system been implemented within your organization?

Has it been effective? What are some positive results since implementing the system?

What do you feel is the manager's responsibility in order to have an effective quality system? Or what does a manager have to do?

What have you, as a manager, done to ensure that employees are aware of and operate under the MSFC quality management system?

Do you feel you have the resources available to your organization to effectively product quality products?

What are your current in-scope activities?

What are your products? Who are your customers?

Are there any records maintained in your office? Who is the custodian?

Do you have any new employees?

Is there any specific training required for your employees? Do they have a training plan?

What is MSFC's Quality Policy?

Who is the Center's ISO Management Representative?

Do you have Customer Feedback System? Corrective Action? Performance Measurement Systm?

4.7Safty Audit Check List

The Customer and Employee Relations Directorate is adopting the Center's Safety Goal – Establish MSFC as Number One in Safety Within NASA.

- Safety Objective – Zero lost time mishaps; no OSHA recordable violations; no safety related property damage greater than $1M; and no inflight safety anomalies.

- Know how to report safety problems. First to supervisor and if no action taken, then SCRS Reporting System.

- Know your rights and responsibilities.

- Know what OSHA stands for – Occupational Safety and Health Administration.

- Know what VPP stands for – Voluntary Protection Program.

- Know what a Materials Safety Data Sheet (MSDs) is.

- Know what the SHE stands for – **Safety, Health and Environmental**.

- Be able to locate your safety records. These are considered Quality Records and should be kept for three years.

- Be sure to use the updated version of MSFC Form 4286 (Jan. 2002) when conducting your monthly safety inspections. Record your walk thrus in SSWP and place the form in the file. Retain for 3 years.

- MPG 8715.1 is the Marshall Safety, Health, and Environmental (SHE) Program guideline. All safety related items for the Center are listed in this document. A good source of reference.

- All employees should be familiar with the evacuation route for their floor.

- Emergency phone numbers are posted on all phones at MSFC.

- Housekeeping rules are to be posted in a general area and followed.

- Post permits (MSFC Form 3798) for heat producing appliances.

- No power strips or extension cords connected in a series.

- Each employee should have a Job Hazard Analysis (JHA).

- Be sure to keep your safety sign in sheets from your monthly safety meeting.

Remember: Safety is everyone's responsibility. Any employee has the right to stop an unsafe action.

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ISO Function Leads' Responsibilities

Function	Requirements
Organization Representatives (Primary)	1. CaER ISO implementation team member 2. Ensure CDXX meet MSFC, CaER ISO requirements 3. Oversight CDXX ISO implementation, Audit preparation 4. Ensure all ISO Function leads provide proper support
Organization Representatives (Alternate)	1. Provide Lead function when Primary representative is not available 2. Provide Proper support that CDXX OPR needs for ISO implementation, and Audit preparation 3. Provide Consultant to Primary OPR and ensure that CDXX meets the ISO requirement
Document Custodian	1. Ensure that CDXX Document Control process meet the Center Requirement
CDxx-OSI-00X	1. Ensure CDXX Consolidated OWI updated when necessary 2. Ensure that CDXX process owners review the process and make the updates
Record Custodan	1. Knowledgeable about all CDXX Record Management 2. Ensure that all Process Owner provide correct information on the record retention schedule. (What, where, and when) 3. Maintain Record Retention Schedule
Safety Coordinator	1. Provide Records for Safety meeting 2. Keep CDXX Safety walk through and other Safety records
Credit Card Owner	1. Knowledgeable about MSFC Credit Card Process Procedure 2. Keep Records on Credit Card Purchase
Export Control Officer (Primary)	1. Knowledgeable about Center Export Control Process 2. Keep Export Control Records 3. Know how to address Export control element within the Tech TracS
Export Control Officer (Alternate)	1. Knowledgeable about Export Control Process 2. Be alternate to the Primary Export Control Officer when Primary officer is not available 3.

Internal/Internal Auditor	1. Provide internal/internal Audit for CDXX 2. Knowledgeable about all ISO requirements 3. Ensure that all CDXX employees, contractors are ready for the Audit in August

5.0 Acronym list

5.1 Document Control Custodian (DCC) The primary and alternate individual(s) responsible for processing and maintaining OWI's and Master lists. The DCC shall maintain the original signed hard copy of OWI's generated within the DCC's organizational element as a quality record. The DCC is responsible for assigning unique document numbers for new OWI's. Owl's will be numbered as follows: OOOO-XXX-YYY; OOOO indicates organization code, XXX indicates the type of organizational issuance (e.g., OWI), and YYY indicates the sequential number beginning with 001. The Organizational manager will appoint a DCC and Alternate for the organization.

5.2 Master List (s) The list of Organizational Work Instructions, applicable documents and other organizational issuances. The master list contains information regarding document number, title, effective date, location, and Office of Primary Responsibility (OPR).

5.3 Organizational Work Instruction (OWI) A document which defines the organizational process and Procedure. It is recommended to use the MSFC Organizational Issuances template.

5.4 Organizational Issuances (OI) Types of OI's include organizational work instructions, technical documents, forms, or special reports, and records.

5.5 M

5.6 Office of Primary Responsibility(OPR)Designee The author or other person responsible for maintaining the accuracy and currency of the OWIs from draft release through all follow-on actions.

5.7 Process Owner (PO) The individual who is responsible for a specific process within an OWI. The PO is responsible for maintaining the accuracy and currency of the data for the process. If the OWI contains only one process, then the OPR and the PO will be the same individual. If the OWI contains multiple processes, then the OPR will consolidate

and integrate all the data, provided from the individual PO's.

5.8 Quality Records. A "record", of any kind, that furnishes objective evidence of activities performed or results achieved. That is, its nature is to capture something that has already happened.

5.9 Quality Records custodian. The individual who is responsible for maintaining the quality records (This person can be document control custodian, process owner, or others)

5.10 Quality Objectives

Those objectives that need to meet requirements for product are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.